

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re Actos Antitrust Litigation

No. 13-CV-9244 (RA)

OPINION & ORDER
ADOPTING REPORT AND
RECOMMENDATION

RONNIE ABRAMS, United States District Judge:

Before the Court are objections to a report and recommendation (“Report”) advising that it grant class certification motions in two antitrust actions—*In re Actos End Payor Antitrust Litigation*, No. 13-CV-9244 and *In re Actos Direct Purchaser Antitrust Litigation*, No. 15-CV-3278—that stem from the allegedly improper delay of generic drugs’ market entry. For the reasons that follow, the Court adopts the recommendations and certifies the proposed end-payor and direct-purchaser classes.

BACKGROUND

The Court assumes the reader’s familiarity with the underlying facts and procedural history of these consolidated cases, about which the Court has written extensively.¹ As Judge Aaron did in the Report, the Court relies on a lengthy excerpt from the Second Circuit’s decision in *United Food & Commercial Workers Local 1776 & Participating Employers Health & Welfare Fund v. Takeda Pharmaceutical Co.* for the regulatory and factual background of these cases. 11 F.4th 118, 124–28 (2d Cir. 2021).²

¹ That writing includes *In re Actos End Payor Antitrust Litig.*, No. 13-CV-9244, 2015 WL 5610752, at *1–9 (S.D.N.Y. Sept. 22, 2015), *aff’d in part, vacated in part*, 848 F.3d 89 (2d Cir. 2017); *In re Actos End Payor Antitrust Litig.*, 417 F. Supp. 3d 352, 357–58 (S.D.N.Y. 2019); and *In re Actos Direct Purchaser Antitrust Litig.*, 414 F. Supp. 3d 635, 638–41 (S.D.N.Y. 2019).

² Like Judge Aaron, the Court has excluded footnotes and record quotations and citations for the sake of brevity. It has also removed explanatory parentheticals. Although Defendants contest certain components of this background section, the Court need not address those contentions as this section is included only for context.

I. Regulatory Background

Under the Federal Food, Drug, and Cosmetic Act, brand-name drug manufacturers must obtain FDA approval to sell a new drug. 21 U.S.C. §§ 301–399. To do so, a manufacturer needs to file a New Drug Application (“NDA”), which includes among other information “a full list of the articles used as components of such drug” and “a full statement of the composition of such drug.” 21 U.S.C. § 355(b)(1). If the new drug either is or contains a patented substance, the pharmaceutical company that owns the patent enjoys market exclusivity for the drug co-extensive with the patent’s protection.

Meanwhile, the Hatch-Waxman Act simplifies the regulatory hurdles for prospective generic drug manufacturers by eliminating the need to file lengthy and costly NDAs. As a result, generic manufacturers need only file an Abbreviated New Drug Application (“ANDA”), which allows the applicant to rely on the FDA’s previous safety and effectiveness findings for the brand drug they wish to replicate and bring to market. 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv). Still, generics are prohibited from infringing the brand’s patents; when a generic competitor submits an ANDA, it must provide a “certification” with respect to each unexpired patent related to the brand drug’s production. The certification alerts the FDA to the relevant patent and explains why the proposed generic would not infringe it.

The Hatch-Waxman Act envisions two types of certifications, each providing a separate regulatory route for the production of a generic drug despite a brand pharmaceutical company’s patent related to the drug. The first is commonly referred to as a “Paragraph IV” certification. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). This certification states that the patent “is invalid or will not be infringed by the manufacture, use, or sale of the new drug.” *Id.* The second is a “Section VIII” certification. 21 U.S.C. § 355(j)(2)(A)(viii). A Section VIII certification is appropriate where the

generic company seeks only to market an unpatented *method* of using a substance in the public domain and certifies that it will “carve out” patented methods from its drug’s production and labeled uses. *Id.*

Relevant to this case, Paragraph IV certifications activate powerful rights and restrictions on behalf of the patent-holding company. As an initial matter, it triggers a “highly artificial act of infringement,” permitting the brand manufacturer to sue the ANDA applicant. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). If the brand chooses to sue, the FDA is automatically prevented from approving the ANDA for the earlier of thirty months or the outcome of the litigation. The wait may be worth it, however, because the statute awards a 180-day period of market exclusivity to the first generic Paragraph IV ANDA applicant who is either not sued or who proves the patent invalid or not infringed by the generic. The exclusivity period begins to run “after the date of the first commercial marketing of the drug” by that generic applicant. 21 U.S.C. § 355(j)(5)(B)(iv). This imposed delay oftentimes creates a bottleneck effect of generic competitors who are ready and willing—but legally unable—to enter the market.

The consequences of filing a Section VIII certification, on the other hand, are much less dramatic. The process entails neither a 30-month litigation stay nor a 180-day exclusivity period. Thus, a generic manufacturer that files a Section VIII certification can more easily enter the market without delay.

Whether the generic manufacturer files a Paragraph IV certification or a Section VIII certification depends on *how* the brand drug manufacturer identifies the object patent(s) to the FDA. During the period relevant to this case, the specific language that a brand looked to in making this decision was found in the Hatch-Waxman Act’s so-called “Listing Requirement” of 21 U.S.C. § 355(b)(1). In relevant part, that section provided:

The applicant shall file with the application the patent number and the expiration date of any patent *which claims the drug* for which the applicant submitted the application or *which claims a method of using such drug* and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

Id. Related to the statutory Listing Requirement, an FDA regulation provides:

An applicant . . . must submit to its NDA the required information . . . for each patent that claims the drug or a method of using the drug that is the subject of the NDA or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. For purposes of this part, such patents consist of drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents. . . .

For patents that claim a drug product, the applicant must submit information only on those patents that claim the drug product, as is defined in § 314.3, that is described in the pending or approved NDA.

For patents that claim a method of use, the applicant must submit information only on those patents that claim indications or other conditions of use for which approval is sought or has been granted in the NDA. The applicant must separately identify each pending or approved method of use and related patent claim(s).

21 C.F.R. § 314.53(b)(1).

If the brand manufacturer lists the patent as claiming the drug itself, a generic manufacturer must make a Paragraph IV certification asserting that the patent is invalid, expired, or otherwise will not be infringed by the generic version. For if the patent at issue is valid and current (and actually *claims the drug*), there is no way to produce a bioequivalent generic without infringing the patent. But if the brand manufacturer lists the patent as claiming a method of using the drug, the Section VIII certification affords the generic manufacturer an avenue to immediately produce its proposed drug provided only that the generic does so in a manner different from the patented method.

Because the FDA “lacks both the expertise and the authority to review patent claims,” rendering “its own role with respect to patent listing ministerial,” it does not “independently assess the patent’s scope or otherwise look behind the description authored by the brand.” *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 406–07 (2012). The use of improper designations during this process “therefore throws a wrench into the FDA’s ability to approve generic drugs.” *Id.* at 419.

II. Factual Background

In 1999, the FDA approved Takeda’s Type-2 Diabetes drug Actos, a treatment tablet containing only one active ingredient—pioglitazone. In its NDA for Actos, Takeda listed U.S. Patent 4,687,777 (the “‘777 Patent”), which consisted of pioglitazone and its pharmacologically acceptable salts, as claiming the drug Actos. The ‘777 Patent was set to expire on January 17, 2011, and, in 2007, the Federal Circuit upheld the patent’s validity, thus definitively preventing generic entry into the pioglitazone market until after that expiration date. *See Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007).

Takeda twice supplemented its NDA—in 1999 and 2002—with information about newly-acquired patents: U.S. Patents 5,965,584 (the “‘584 Patent”) and 6,329,404 (the “‘404 Patent”), respectively. Both patents, each set to expire in 2016, cover unique compounds containing pioglitazone *and* another active ingredient that, together, yield novel synergies not offered by pioglitazone alone. Specifically, the ‘584 and ‘404 Patents are “[p]harmaceutical composition[s] which comprise[] an insulin sensitivity enhancer in combination with other antidiabetics . . . which shows a potent depressive effect on diabetic hyperglycemia.” Because they are amalgams of separately identifiable constituent parts, both ‘584 and ‘404 are properly called “combination patents.” *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 339 (1961).

In its supplements for the Actos NDA, Takeda told the FDA that these combination patents both *claim the drug* Actos in addition to *claiming methods of using* Actos. Under normal circumstances, this would have compelled generic drug makers seeking to compete in the Actos market to file Paragraph IV certifications because one would have to undermine the validity of the ‘584 and ‘404 patents for the FDA to grant the ANDA. Complicating matters in this case, however, when the FDA published Takeda’s supplemental patent information in its Orange Book—the “go-to source of brand patent information”—it listed the ‘584 and ‘404 Patents only as method-of-use patents. *In re Actos End-Payor Antitrust Litigation*, 848 F.3d at 98–99. Presumably, then, there was no reason at that time for a generic Actos maker to believe that a Paragraph IV certification was required for FDA approval.

Nevertheless, in 2003, three generic manufacturers seeking to introduce a bioequivalent pioglitazone drug filed ANDAs containing Paragraph IV certifications with respect to patents ‘584 and ‘404. These companies agreed to share “first filer” status for purposes of the exclusivity period in marketing a generic version of Actos. Although their motivations for making this unnecessary certification remain unconfirmed, the competitive advantage from being a first filer under Paragraph IV for a generic Actos drug certainly provided a valuable incentive for doing so. Takeda thereafter sued the three generics for patent infringement. After a trial, the district court entered judgment for Takeda solely based on the ‘777 Patent’s continuing validity and enforceability but did not address the validity or enforceability of the combination patents. *Takeda Chem. Indus., Ltd. v. Ranbaxy Labs., Ltd.*, No. 03-CV-8250, 2006 WL 618424, at *1–2 (S.D.N.Y. Mar. 13, 2006).

Other generics, however, refused to make Paragraph IV certifications to the purported drug product claims and instead addressed only the method-of-use claims using Section VIII statements. For example, Teva Pharmaceuticals filed a Section VIII certification in July 2004, hoping that

doing so would permit it to manufacture a non-infringing generic Actos without regard to any 180-day exclusivity period. This would have allowed Teva to come to market immediately upon the ‘777 patent’s expiration, while the Paragraph IV certification filers would have to wait.

Yet another generic drug manufacturer, Sandoz, Inc., filed a citizen petition with the FDA, asserting that Takeda had improperly caused the FDA to list the ‘584 and ‘404 patents in the Orange Book as drug product patents for Actos. It therefore asked that the FDA require all ANDA filers to make Paragraph IV certifications in order to level the playing field among generics. At the FDA’s behest, Takeda responded to the petition by reaffirming that it correctly listed the two patents as claiming both Actos as well as specific methods of its use. In light of Takeda’s response, the FDA granted Sandoz, Inc.’s citizen petition and ruled that it would not approve a generic Actos ANDA that did not contain a Paragraph IV certification.

As a result of these events, robust generic competition for Actos was allegedly improperly delayed for almost two years past January 17, 2011, when the ‘777 Patent expired. Consolidated class actions followed.

III. Procedural Background

In March 2018, indirect purchasers of Actos and its generics (“End-Payor Plaintiffs” or “EPPs”), including consumers and third-party payors, filed a fourth amended complaint against Takeda Pharmaceutical Company Limited, Takeda America Holdings, Inc., Takeda Pharmaceuticals U.S.A., Inc. and Takeda Development Center Americas, Inc. (collectively, “Takeda”). Dkt. 255.³ The EPPs allege that Takeda violated the antitrust laws of 20 States, the

³ Unless stated otherwise, all record citations are to Docket Number 13-CV-9244.

District of Columbia, and Puerto Rico (collectively, “Class States”).⁴ In November 2019, direct purchasers of Actos and its generics (“Direct-Purchaser Plaintiffs” or “DPPs”) filed their fourth amended complaint, alleging that Takeda violated Section 2 of the Sherman Act, 15 U.S.C. § 2. No. 15-CV-3278, Dkt. 152.

On January 17, 2024, the EPPs and DPPs filed motions to certify classes in their respective actions. The proposed EPP class consists of the following:

All entities that, for consumption by their members, insureds, or beneficiaries, paid and/or provided reimbursement for some or all of the purchase price of Actos or generic pioglitazone in the [Class States], other than for resale, at any time from January 17, 2011 through and until December 31, 2015; and all individuals who paid for some or all of the purchase price of Actos in the [Class States] at any time from January 17, 2011 through and until December 31, 2015.

EPPs’ Mot. to Certify at 1–2, Dkt. 587. The proposed class excludes (1) Defendants and their subsidiaries and affiliates; (2) federal and state governmental entities; (3) judges assigned to the case, their chambers’ staff, and any members of the judges’ or chambers staff’s immediate family; (4) Defendants’ officers, directors, and employees; (5) individuals who after August 17, 2012 (the actual generic entry date) purchased only Actos and did not purchase generic pioglitazone; and (6) any “flat copay” consumers who purchased Actos only via a fixed dollar copayment that does not vary on the basis of the drug’s status as brand or generic. *Id.*

The proposed DPP class consists of the following:

All persons or entities in the United States and its territories and possessions, including the Commonwealth of Puerto Rico, who purchased Actos or its AB-rated generic equivalent directly from Defendants or any generic manufacturer at any time on or after January 17, 2011 through January 31, 2013.

⁴ The “Class States” include Arizona, California, Illinois, Iowa, Maine, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Utah, West Virginia, and Wisconsin, as well as the District of Columbia and the Commonwealth of Puerto Rico.

DPPs’ Mot. to Certify at 1, Dkt 589. The proposed class excludes (1) Defendants and their officers, directors, management, employees, subsidiaries, and affiliates; (2) all governmental entities; (3) Drogueria Bayamon and Drogueria Central; as well as (4) Belldina’s Healthmart Pharmacy. *Id.*

On August 9, 2024, Magistrate Judge Stewart Aaron issued a report and recommendation on both certification motions. Dkt. 763. He recommended that the Court grant both the EPPs’ and DPPs’ motions for class certification. Takeda timely filed objections to the Report on August 30, 2024, Dkt. 771, to which the EPPs and DPPs responded on September 20, 2024, Dkts. 791 & 793. Takeda’s objections are now before the Court.

LEGAL STANDARD

I. Review of Report & Recommendation

A district court “may accept, reject, or modify, in whole or in part, the findings or recommendations made by [a] magistrate judge.” 28 U.S.C. § 636(b)(1)(C); *see* Fed. R. Civ. P. 72(b)(3).⁵ If a party files specific and timely objections to a magistrate judge’s findings or recommendations, a district judge reviews those findings or recommendations *de novo*, rather than for clear error. *See* 28 U.S.C. § 636(b)(1)(C); Fed. R. Civ. P. 72(b)(3); *id.* advisory committee’s notes; *Ortiz v. Comm’r of Soc. Sec.*, No. 22-CV-3052, 2023 WL 8603327, at *1 (S.D.N.Y. Dec. 12, 2023). By contrast, where “objections are nonspecific or merely perfunctory responses . . . argued in an attempt to engage the district court in a rehashing of the same arguments set forth in the original petition,” the clear error standard applies. *Miller v. Brightstar Asia, Ltd.*, 43 F.4th 112, 120 (2d Cir. 2022).

⁵ Unless otherwise indicated, this opinion and order omits all internal quotations marks, citations, footnotes, omissions, emphases, and alterations in quoted text.

II. Class Certification

To succeed on a motion for class certification, the movant must establish what are commonly known as the “numerosity, commonality, typicality, and adequate representation” requirements of Rule 23(a): that “(1) the class is so numerous that joinder of all members is impracticable; (2) there are questions of law or fact common to the class; (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and (4) the representative parties will fairly and adequately protect the interests of the class.” *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 345, 349 (2011); Fed. R. Civ. P. 23(a).

In addition, the movant “must satisfy at least one of the three requirements listed in Rule 23(b).” *Wal-Mart Stores, Inc.*, 564 U.S. at 345. As relevant here, under Rule 23(b)(3), the movant must establish that (1) “questions of law or fact common to class members predominate over any questions affecting only individual members” and (2) “a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.” Fed. R. Civ. P. 23(b)(3). The Second Circuit “has also recognized an implied requirement of ascertainability in Rule 23, which demands that a class be sufficiently definite so that it is administratively feasible for the court to determine whether a particular individual is a member.” *In re Petrobras Sec.*, 862 F.3d 250, 260 (2d Cir. 2017).

Determining whether a movant has satisfied the requirements of Rule 23—which it must do by a preponderance of the evidence, *see Teamsters Loc. 445 Freight Div. Pension Fund v. Bombardier Inc.*, 546 F.3d 196, 202 (2d Cir. 2008)—requires a “rigorous analysis,” *Comcast Corp. v. Behrend*, 569 U.S. 27, 33 (2013).

DISCUSSION

Takeda objects to the recommendations that the Court grant the EPPs’ and DPPs’ motions for class certification on numerous grounds. The Court begins with the objections related to the EPPs’ motion, followed by those related to the DPPs’ motion.⁶

I. End-Payor Plaintiffs’ Class Certification Motion

Takeda urges the Court not to certify the class of EPPs for three primary reasons. *First*, it argues that the Court lacks personal jurisdiction over Takeda with respect to the claims of the unnamed class members. *Second*, it contends that the EPPs failed to satisfy Rule 23(b)(3)’s requirement that “questions of law or fact common to class members predominate over any questions affecting only individual members.” Fed. R. Civ. P. 23(b)(3). *Third*, it maintains that the proposed methodology for determining class eligibility would violate its right to due process. The Court is not persuaded.

A. Personal Jurisdiction

Takeda objects to Judge Aaron’s conclusion that it need only consider whether the Court has personal jurisdiction over it with respect to the claims of the named plaintiffs. Citing two cases—*Cold Industries Shareholder Litigation v. Colt Industries Inc.*, 556 N.E.2d 1160, 1165, 1167 (N.Y. 1991) and *Levy Investments, Ltd. v USI Holdings*, No. 1011/07, 2007 WL 7321658, at

⁶ Takeda objects to the report and recommendation on the basis that Judge Aaron improperly applied a “liberal construction” of Rule 23, under which there is a “preference” for certification. Report at 13. It maintains that courts must conduct a rigorous analysis. The standard applied by Judge Aaron is entirely consistent with the law of the Second Circuit. “The Second Circuit has emphasized that Rule 23 should be given liberal rather than restrictive construction, and it seems beyond peradventure that the Second Circuit’s general preference is for granting rather than denying class certification.” *Espinoza v. 953 Assocs. LLC*, 280 F.R.D. 113, 124 (S.D.N.Y. 2011); see *Marisol A. v. Giuliani*, 126 F.3d 372, 377 (2d Cir. 1997); *Pichardo v. Carmine’s Broadway Feast Inc.*, No. 15-CV-3312, 2016 WL 4379421, at *4 (S.D.N.Y. June 13, 2016), *report and recommendation adopted*, 2016 WL 5338551 (S.D.N.Y. Sept. 23, 2016). Regardless, Judge Aaron recognized his obligation to conduct a rigorous analysis, Report at 13, 31, and the Court has no doubt that he fulfilled that obligation. His plainly rigorous analysis is evidenced by his careful review of the record, including lengthy expert reports; his decision to hold an all-day hearing; and, most clearly, by his thorough and well-reasoned 81-page report and recommendation.

*13 (N.Y. Sup. Ct. Mar. 28, 2007)—it argues that “New York courts have strongly suggested that they would analyze” whether personal jurisdiction exists as to unnamed class members’ claims. Objections at 24. It also asserts that, following the Supreme Court’s decision in *Bristol-Myers Squibb Company v. Superior Court of California*, due process requires a court to have personal jurisdiction as to the claims of unnamed class members. 582 U.S. 255 (2017).

The Court agrees with Judge Aaron that *Colt Industries* and *Levy* are inapposite to the cases at hand. Although “the law of the forum in which the court sits” determines “[p]ersonal jurisdiction over a defendant in a diversity action,” *Colt Industries* did not address New York’s law on personal jurisdiction. *CutCo Indus., Inc. v. Naughton*, 806 F.2d 361, 365 (2d Cir. 1986). It instead pertained to out-of-state class members’ federal constitutional right to opt out of a class—which provides no “strong[] suggest[ion]” that this Court must assess whether it has personal jurisdiction with respect to the claims of unnamed class members. Objections at 24.

Levy is likewise unpersuasive. In *Levy*—which involved a preliminary injunction—a justice of the New York State Supreme Court observed that he could not conclude that monetary damages would be an inadequate remedy even if the case proceeded as a class action. 2007 WL 7321658, at *13. He reasoned in part that the court “*m[ight]* lack personal jurisdiction” as to the claims of out-of-state plaintiffs. *Id.* (emphasis added). This *dicta*—in a lower court’s decision that does not bind this Court—is far from the “strong[] suggest[ion]” Takeda purports to identify. Objections at 24.

The Court further agrees with Judge Aaron that *Bristol-Myers Squibb* does not require it to consider whether it has personal jurisdiction as to the claims of unnamed class members. 582 U.S. 255 (2017). In *Bristol-Myers Squibb*—a mass action rather than a class action—the Supreme Court held that the due process requirements of the Fourteenth Amendment prohibited California state

courts from exercising specific personal jurisdiction with respect to the claims of out-of-state plaintiffs. *Id.* at 264, 268. Contrary to Takeda’s argument that Second Circuit law requires the Court to consider personal jurisdiction as to the claims of unnamed class members, the Circuit has yet to rule on how *Bristol-Myers* applies to such claims. But the two courts of appeals to directly address the issue—the Seventh and Sixth Circuits—have each concluded that *Bristol-Myers Squibb* does not require unnamed class members to establish personal jurisdiction. *See Mussat v. IQVIA, Inc.*, 953 F.3d 441, 447–48 (7th Cir. 2020); *Lyngaas v. Curaden Ag*, 992 F.3d 412, 433–36 (6th Cir. 2021). The Third Circuit has similarly agreed “that *Bristol-Myers* did not change the personal jurisdiction question with respect to class actions.” *Fischer v. Fed. Express Corp.*, 42 F.4th 366, 375 (3d Cir. 2022), *cert. denied*, 143 S. Ct. 1001 (2023).

Like Judge Aaron, this Court finds *Mussat*, *Lyngaas*, and *Fischer* persuasive, along with the similar decisions of many district courts. *See Hines v. Equifax Info. Servs. LLC*, No. 19-CV-6701, 2024 WL 4132333, at *2 (E.D.N.Y. Sept. 10, 2024); *Chernus v. Logitech, Inc.*, No. 17-CV-673, 2018 WL 1981481, at *7 (D.N.J. Apr. 27, 2018) (collecting cases); *Hines v. Equifax Info. Servs., LLC*, No. 19-CV-6701, 2022 WL 2841909, at *14 (E.D.N.Y. July 16, 2022) (same), *report and recommendation adopted as modified*, No. 19-CV-6701, 2024 WL 4132333 (E.D.N.Y. Sept. 10, 2024); *see also* Daniel Wilf-Townsend, *Did Bristol-Myers Squibb Kill the Nationwide Class Action?*, 129 Yale L.J. Forum 205, 208 (2019) (finding that “a large supermajority of courts to consider the issue have held that the exercise of personal jurisdiction in nationwide class actions continues to be permissible in much the same way as it was before [*Bristol-Myers Squibb*]”).⁷

⁷ Takeda also objects to the alternative rationale that it consented to personal jurisdiction as to the claims of the unnamed class members through the following response to jurisdictional allegations in the EPPs’ fourth amended complaint: “Paragraph 12 states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that personal jurisdiction exists in this case.” Answer ¶ 12, Dkt. 279.

On this point, the Court agrees with Takeda. Takeda’s answer to Paragraph 12 of the complaint did not specifically reference unnamed class members. And while consent to personal jurisdiction can be “express or implied,” the Court

As the court in *Mussat* observed, “[c]lass actions . . . are different from many other types of aggregate litigation.” 953 F.3d at 446–47. “[T]he lead plaintiffs earn the right to represent the interests of absent class members.” *Id.* at 447. “[A] class action is formally one suit in which, as a practical matter, a defendant litigates against only the class representative.” *Lyngaas*, 992 F.3d at 435. “[A]bsent class members,” moreover, “are not considered parties, as a class representative is, for certain jurisdictional purposes,” *id.*, including diversity jurisdiction, *see Devlin v. Scardelletti*, 536 U.S. 1, 10 (2002); *see also id.* (“The label party does not indicate an absolute characteristic, but rather a conclusion about the applicability of various procedural rules that may differ based on context.”). They should likewise not be considered parties for the purpose of personal jurisdiction. *See Mussat*, 953 F.3d at 447; *Lyngaas*, 992 F.3d at 437; *Fischer*, 42 F.4th at 375.

Although the Court finds these distinctions and analogies persuasive, it appreciates that there are strong arguments supporting a conclusion contrary to the one it reaches today. Still, in light of the case law cited above, it declines to upend the “longstanding practice” permitting class actions to move forward under the circumstances present here. *Hines*, 2024 WL 4132333, at *3.

Takeda’s argument about the Rules Enabling Act does not alter this conclusion. The Rules Enabling Act “instructs that rules of procedure shall not abridge, enlarge or modify any substantive right.” *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 613 (1997). Takeda maintains that failing to consider personal jurisdiction as to the claims of unnamed class members would abridge its due process right to challenge the Court’s jurisdiction as to those claims. While this argument, too, has some appeal, Takeda cites little case law supporting it. The two Supreme Court decisions it cites—

does not find implied consent here. *Ins. Corp. of Ir. v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 703 (1982). Unlike the EPPs’ answer to Paragraph 12, its fifth affirmative defense references “putative class members.” Answer at 27. In addition, unnamed class members are not party to an action until certification. *See Moser v. Benefytt, Inc.*, 8 F.4th 872, 877–78 (9th Cir. 2021); *Cruson v. Jackson Nat’l Life Ins. Co.*, 954 F.3d 240, 250–51 (5th Cir. 2020); *Molock v. Whole Foods Mkt. Grp., Inc.*, 952 F.3d 293, 297–98 (D.C. Cir. 2020); *Shaw v. Hornblower Cruises & Events, LLC*, No. 21-CV-10408, 2023 WL 3738731, at *4–5 (S.D.N.Y. May 31, 2023).

Amchem Products, 521 U.S. at 613 and *Wal-Mart Stores*, 564 U.S. at 367—do not directly address the question presented here. Furthermore, courts have found that “class action[s] do[] not abridge any substantive due process rights such that the maintenance of a class action violates the Rules Enabling Act.” *Samson v. United Healthcare Servs. Inc.*, No. 19-CV-00175, 2024 WL 866815, at *5 (W.D. Wash. Feb. 29, 2024); *see id.* (collecting cases); *Al Haj v. Pfizer Inc.*, 338 F. Supp. 3d 815, 822 (N.D. Ill. 2018).

Accordingly, the Court rejects the argument that the EPPs must have established personal jurisdiction with respect to the claims of unnamed class members to obtain class certification.

B. Predominance

Takeda next asserts that the EPPs failed to prove that “questions of law or fact common to class members predominate over any questions affecting only individual members.” Fed. R. Civ. P. 23(b)(3).

1. Class Member Identification

In particular, Takeda contends that individual questions predominate because identifying eligible class members will involve a “multistep process centered on the submission and detailed evaluation of individual affidavits for more than 300,000 class members.” Objections at 33.

The essence of the predominance inquiry under Rule 23(b)(3) is whether a proposed class is “sufficiently cohesive to warrant adjudication by representation.” *Amgen Inc. v. Conn. Ret. Plans & Tr. Funds*, 568 U.S. 455, 469 (2013). A putative class satisfies Rule 23(b)(3) “if[] (1) resolution of any material legal or factual questions . . . can be achieved through generalized proof, and (2) these [common] issues are more substantial than the issues subject only to individualized proof.” *In re Petrobras Sec.*, 862 F.3d at 270. “The distinction between individual and common

questions is thus central to the predominance analysis.” *Id.* As the Supreme Court explained in *Tyson Foods, Inc. v. Bouaphakeo*:

An individual question is one where members of a proposed class will need to present evidence that varies from member to member, while a common question is one where the same evidence will suffice for each member to make a *prima facie* showing or the issue is susceptible to generalized, class-wide proof.

577 U.S. 442, 453 (2016). The court’s predominance “analysis is more qualitative than quantitative and must account for the nature and significance of the material common and individual issues in the case.” *In re Petrobras Sec.*, 862 F.3d at 271; *see also Tyson Foods*, 577 U.S. at 453 (explaining that the court must “ask[] whether the common, aggregation-enabling, issues in the case are more prevalent or important than the non-common, aggregation-defeating, individual issues”); *Haley v. Tchrs. Ins. & Annuity Ass’n of Am.*, 54 F.4th 115, 121 (2d Cir. 2022) (explaining that the predominance inquiry “is not simply an exercise in tallying up issues”).

Relevant to Takeda’s argument, “[i]f . . . too much individual inquiry is required to determine whether someone is a member of the class, then a court could find that class issues do not predominate over individual issues.” *Vogel v. City of New York*, No. 14-CV-9171, 2017 WL 4712791, at *5 (S.D.N.Y. Sept. 19, 2017); *see Decastro v. City of New York*, No. 16-CV-3850, 2019 WL 4509027, at *13 (S.D.N.Y. Sept. 19, 2019). And here, individual inquiry is necessary to determine class eligibility. According to EPP expert Laura Craft, data is available to identify class members, whose membership can be confirmed through a claim form that includes an affidavit. Craft Report ¶¶ 12, 17, Dkt. 605. Although “[d]ata relating to prescription drug transactions is . . . highly standardized,” *id.* ¶ 13, the data submitted by each member will be specific to that class member—and thus, to an extent, will “var[y] from member to member,” *Tyson Foods*, 577 U.S. at 453.

The Court nonetheless concludes that the common issues are “more substantial.” *In re Petrobras Sec.*, 862 F.3d at 270. As the Supreme Court has observed, “[p]redominance is a test readily met in certain cases alleging . . . violations of the antitrust laws.” *Amchem Prods.*, 521 U.S. at 625; *see Cordes & Co. Fin. Servs. v. A.G. Edwards & Sons, Inc.*, 502 F.3d 91, 108 (2d Cir. 2007). Core elements of the EPPs’ antitrust claims—(1) a violation of antitrust law; (2) antitrust injury; and (3) damages, *see Cordes & Co. Fin. Servs.*, 502 F.3d at 105—are common questions.⁸

As Judge Aaron explained, the evidence supporting the first factor will be the same for each class member, as it will consist of evidence regarding Takeda’s conduct. Judge Aaron was also correct to view the second element as a common issue here. The question of antitrust injury involves two questions. *Id.* at 106. The first question is a “factual” one that asks whether the plaintiff suffered injury. *Id.* Here, the EPPs will seek to prove class-wide injury using a common two-step approach that itself relies on common evidence: economic literature, forecasts by Takeda and generic manufacturers, and data on the launch of the generic. Conti Report ¶¶ 42, 55, Dkt 588. The second question is a “legal” one that asks whether the “injury [is] of the type the antitrust laws were intended to prevent and . . . flows from that which makes defendants’ acts unlawful.” *Cordes & Co. Fin. Servs.*, 502 F.3d at 106. Here, this legal question is a common one because the EPPs allege the same injury—their payment of higher prices due to Takeda’s conduct. *See id.* at 107.

⁸ Judge Aaron observed “that each of the relevant state antitrust statutes has language similar to the Sherman Act and/or has been effectively harmonized [with the Act], such that the elements of the . . . claim[s] are effectively the same.” Report at 38. Takeda did not object to this conclusion. Nonetheless, aided by the EPPs’ chart of applicable state antitrust laws, Dkt. 667, the Court has reviewed the state provisions and case law supporting the conclusion in depth and agrees with Judge Aaron.

The Court also recognizes that assessing statutory standing under the relevant state statutes will require individual, albeit limited, inquiry. That individual inquiry may, for example, simply require the review of standardized data Craft identifies as relevant to the identification of class membership. As she explains, the standardized data indicates the location of a transaction. *See* Craft Report ¶ 48.

The EPPs will also use common evidence to establish the third element of damages. A plaintiff in an antitrust class action may establish damages through aggregate damages so long as the aggregate damages “roughly reflect” the “amount owed to class members.” *Seijas v. Republic of Argentina*, 606 F.3d 53, 58–59 (2d Cir. 2010); *see Hickory Secs. LTD. v. Republic of Argentina*, 493 F. App’x 156, 158–59 (2d Cir. Aug. 14, 2012); *In re Namenda Indirect Purchaser Antitrust Litig.*, No. 15-CV-6549, 2022 WL 4298767, at *9 (S.D.N.Y. Sept. 19, 2022). As Judge Aaron accurately observed, EPP expert Rena Conti employs a “common yardstick methodology . . . to model how generic entry would have affected prices and quantities sold of Actos and its generic[s] . . . absent the delayed generic entry.” Report at 50; *see* Conti Report ¶¶ 78–105. She employs data from the launch of the generic, Conti Report ¶¶ 81–87, and then calculates the gross overcharges using industry data of retail sales, also accounting for several offsets, *id.* ¶¶ 89–104. Like Judge Aaron, moreover, this Court “is satisfied,” Report at 52, that Conti’s proposed aggregate damages model will produce a figure that “roughly reflect[s]” the “amount owed to class members,” *Seijas*, 606 F.3d at 58–59.

The cases denying class certification that Takeda cites as analogous to the instant case are distinguishable. *Mazzei v. Money Store*, 829 F.3d 260, 272 (2d Cir. 2016) and *Decastro*, 2019 WL 4509027 at *13 are not antitrust cases, in which the predominance test is commonly “readily met.” *Amchem Prods.*, 521 U.S. at 625. And while *In re Aluminum Warehousing Antitrust Litigation* is an antitrust case, the individual analysis there would have required, among other things, “close analysis of each individual contract and comparison to public pricing data” rather than the review of standardized data. 336 F.R.D. 5, 64–65 (S.D.N.Y. 2020)

The Court thus concludes that the identification of class membership does not preclude a finding that the EPPs satisfied Rule 23(b)(3)’s predominance requirement.

2. Timing of Class Membership Identification

Takeda further objects to Judge Aaron's predominance finding based on the assumption that class membership must be determined before a liability determination is made. In support, it observes that class members "must be ascertainable at some point in the case," claiming that the EPPs propose identifying class members only *after* the case ends. *Merryman v. Citigroup, Inc.*, No. 15-CV-9185, 2018 WL 1621495, at *15 (S.D.N.Y. Mar. 22, 2018). The Court disagrees.

First, the EPPs do not propose identifying class members only after the case ends. Their proposed trial management plan calls for the entry of final judgment only after the EPPs "submit [to the Court] an itemized report . . . that recommends a specific damages allocation among Class members." EPPs' Proposed Trial Management Plan at 7, Dkt 588. Stated differently, the plan does not envision the Court entering final judgment until class members have been identified.

Second, the Court is unaware of any case law indicating that, in these circumstances, class membership must be fully determined before a liability determination is made. Takeda's reliance on *Hunter v. Time Warner Cable Inc.*, No. 15-CV-6445, 2019 WL 3812063, at *10–12 (S.D.N.Y. Aug. 14, 2019) and *Diverse Partners, LP v. AgriBank, FCB*, No. 16-CV-9526, 2019 WL 4305008, at *3–5 (S.D.N.Y. Sept. 11, 2019) is misguided. As Judge Aaron correctly noted, the timing of class member identification in those cases did not bear on the courts' conclusions that the plaintiffs there had failed to satisfy the predominance requirement of Rule 23(b)(3). *See Hunter*, 2019 WL 3812063 at *10–12; *Diverse Partners*, 2019 WL 4305008, at *3–5.

Finally, were it necessary to determine class membership before a liability determination is made, Craft testified that the relevant data would allow class members to identify themselves at "any time." Hearing Tr. 167:22, Dkt. 761 (emphasis added); *see id.* 166:19–22; Craft Report ¶ 90.

The timing of class membership identification thus does not render Judge Aaron's predominance finding erroneous.

3. Administrative Feasibility

Takeda next argues that Judge Aaron's predominance finding is erroneous because he ignored the administrative feasibility of identifying class members. Courts consider the "administrative feasibility of ascertaining [class] membership . . . when determining whether common issues predominate over individual issues." *Hughes v. Ester C. Co.*, 320 F.R.D. 337, 341 (E.D.N.Y. 2017); see *Diverse Partners*, 2019 WL 4305008, at *4 n.4; *Calvo v. City of New York*, No. 14-CV-7246, 2018 WL 1633565, at *8 n.21 (S.D.N.Y. Apr. 2, 2018). Judge Aaron did just that. He credited, as this Court does, Craft's rebuttal testimony that the information relevant to determining class membership was included in the data samples if one "look[s] in the right place." Hearing Tr. 145:18. He also found that potential variation across data sources that would create difficulty or require additional labor was not so concerning so as to defeat the EPPs' predominance showing. The Court agrees and does not otherwise find any administrative feasibility concerns that would alter its conclusion regarding predominance.

Accordingly, the EPPs satisfied Rule 23(b)(3)'s predominance requirement.

C. Due Process

Takeda lastly asserts that the EPPs' process for identifying eligible class members would violate its due process right to challenge whether a purported member is in fact eligible. But Judge Aaron did not conclude that Takeda could not challenge the purported eligibility of a class member. In fact, he explicitly envisioned that Takeda could challenge a class member's eligibility during the claims administration process. See Report at 56 n.56. Furthermore, although the parties are free to further brief this issue at a later juncture, the Court is doubtful that a particular unnamed class

member’s eligibility “implicate[s] [Takeda’s] due process interest at all.” *Mullins v. Direct Digit., LLC*, 795 F.3d 654, 670 (7th Cir. 2015). Nonetheless, to the extent Takeda has any due process right to challenge member eligibility at trial, the Court would modify the EPPs’ proposed trial management plan accordingly. *See In re Petrobras Sec.*, 862 F.3d at 274 (“[W]e emphasize that district courts are authorized to implement management strategies tailored to the particularities of each case.”).

In sum—having rejected all of Takeda’s material objections and otherwise found no clear error—the Court agrees with Judge Aaron’s recommendation that it grant the EPPs’ class certification motion.

II. Direct-Purchaser Plaintiffs’ Class Certification Motion

As to the remaining class certification motion, Takeda maintains that the DPPs failed to satisfy the Rule 23(a)(1) requirement that “the class [be] so numerous that joinder of all its members is impracticable.” Fed. R. Civ. P. 23(a)(1). In particular, it argues that Judge Aaron (1) erroneously found that the class contained at least 40 members and (2) misevaluated the factors relevant under *Robidoux v. Celani*, 987 F.2d 931, 936 (2d Cir. 1993). The Court disagrees.

A. Presumptive Numerosity

Takeda contends the Court may not presume numerosity—as it does when a class consists of at least 40 members, *see Consol. Rail Corp. v. Town of Hyde Park*, 47 F.3d 473, 483 (2d Cir. 1995)—because 54 of the 84 putative class members lack antitrust standing.

“To demonstrate antitrust standing, a private plaintiff must show both that (1) it suffered a special kind of antitrust injury and that (2) it is a suitable plaintiff to pursue the alleged antitrust violations and thus is an efficient enforcer of the antitrust laws.” *In re Am. Express Anti-Steering*

Rules Antitrust Litig., 19 F.4th 127, 138 (2d Cir. 2021). Takeda maintains that 54 of the putative class members are not efficient enforcers of the antitrust laws.

“Whether a plaintiff is an efficient enforcer depends on the four factors the Supreme Court identified in [*Associated General Contractors of California, Inc. v. California State Council of Carpenters*, 459 U.S. 519, 540–44 (1983)].” *Id.* “Those factors are (1) the directness or indirectness of the asserted injury; (2) the existence of more direct victims or the existence of an identifiable class of persons whose self-interest would normally motivate them to vindicate the public interest in antitrust enforcement; (3) the extent to which the claim is highly speculative; and (4) the importance of avoiding either the risk of duplicate recoveries on the one hand, or the danger of complex apportionment of damages on the other.” *Id.* “The weight to be given the various factors will necessarily vary with the circumstances of particular cases.” *Id.*

The first factor relies “on familiar principles of proximate causation.” *Id.* at 139. “Proximate cause,” in turn, “generally follows the first-step rule,” *id.*, which “limits liability to parties injured at the first step of the causal chain of the defendants’ actions,” *id.* at 135. Takeda argues that the first-step rule precludes the participation of the 54 putative class members, which—rather than purchase Actos from Takeda—only purchased generics from non-party generic manufacturers. It reasons that its conduct was not at the first step of the causal chain because it did not itself raise generic prices. In support, Takeda relies on *In re American Express*, in which the Second Circuit concluded that that plaintiffs did not suffer antitrust injury because they experienced injury only once *competitors* raised fees in response to American Express’ conduct. There, the Second Circuit observed that American Express’ “enabling” of competitors’ price increases did “not establish the direct relation between injury and antitrust violation that the first-step rule requires.” *Id.* at 141.

Like Judge Aaron, this Court finds *In re American Express* distinguishable. The theory of liability here is not that Takeda’s antitrust violation “enable[ed]” competitors’ price increases, injuring their customers who had to pay more. *Id.* It is more direct: It is that Takeda caused high generic prices to begin with by delaying the formation of a competitive market. Accordingly, this case is more akin to *In re Modafinil Antitrust Litigation*, another market exclusion case. 837 F.3d 238 (3d Cir. 2016), *as amended* (Sept. 29, 2016). There, the Third Circuit reasoned that market customers in a market exclusion case had standing because they “suffer[ed] . . . from the foreclosure of choice”—unlike in a price fixing case, where only direct customers suffer harm. *Id.* at 265; *see also In re HIV Antitrust Litig.*, No. 19-CV-2573, 2022 WL 22609107, at *44–46 (N.D. Cal. Sept. 27, 2022) (relying on similar reasoning); *In re Loestrin 24 Fe Antitrust Litig.*, No. 13-MD-2472, 2019 WL 3214257, at *9 (D.R.I. July 2, 2019) (same).

Takeda also argues that other “efficient enforcer” factors support the conclusion that the 54 putative class members lack antitrust standing. *In re Am. Express*, 19 F.4th at 138. On the logic the Court has already rejected, it asserts that the direct purchasers of Actos from Takeda are “more direct victims” than the 54 putative class members. *Id.* But, as Judge Aaron observed, the direct purchasers are “equally direct” victims of Takeda. Report at 66. They are just direct in a different way.

Takeda further maintains that excluding the 54 putative class members is “importan[t] [for] avoiding . . . the risk of duplicate recoveries” because the EPPs are also suing under state law to recover generic overcharges. *In re Am. Express*, 19 F.4th at 138. Yet, as the DPPs observe, if direct purchasers—“the only entities able to sue Takeda under federal [antitrust] law—cannot recover for overcharges on generic units ‘a substantial portion of the harm attributed to [the] defendant would go unaddressed.’” DPPs’ Response at 12, Dkt. 791 (quoting *In re Relafen Antitrust Litig.*,

346 F. Supp. 2d 349, 369 (D. Mass. 2004)). Moreover, as Judge Aaron observed, the “general view among district courts” is that duplicative recovery is “permissibl[e]” under these circumstances. *In re Propranolol Antitrust Litig.*, 249 F. Supp. 3d 712, 726 (S.D.N.Y. 2017); *see id.* at 726 n.19 (collecting cases). The Court nonetheless finds the fourth factor non-dispositive here, as “the efficient-enforcer inquiry remains, fundamentally, one into proximate cause.” *In re Am. Express*, 19 F.4th at 143.

The Court may thus presume numerosity because the DPP class contains at least 40 members. *See Consol. Rail Corp.*, 47 F.3d at 483.

B. Robidoux Factors

Takeda next asserts that, regardless of whether the Court may presume numerosity, the DPPs failed to establish that joinder is impracticable under *Robidoux v. Celani*, 987 F.2d at 936.

While the Court may presume numerosity in the face of 40 class members, “practicability depends on all the circumstances surrounding a case, not on mere numbers.” *Id.* “Relevant considerations include” (1) “judicial economy arising from the avoidance of a multiplicity of actions,” (2) “geographic dispersion of class members,” (3) “financial resources of class members,” (4) “the ability of claimants to institute individual suits,” and—irrelevant here—(5) “requests for prospective injunctive relief which would involve future class members.” *Id.* “[T]he court may make common sense assumptions to support a finding of numerosity, [although] it cannot do so on the basis of pure speculation without any factual support.” *Jeffries v. Pension Tr. Fund of Pension, Hospitalization & Benefit Plan of Elec. Indus.*, 172 F. Supp. 2d 389, 394 (S.D.N.Y. 2001).

Having made such commonsense assumptions and assessed the DPPs’ evidence, the Court agrees with Judge Aaron that, on balance, the circumstances here render joinder impracticable.

Judicial economy favors certification because the Court might otherwise face delay and the need for additional counsel, discovery, and motion practice. For example, while the EPPs and DPPs have together already filed a partial motion for summary judgment, Dkt. 706, declining certification might require briefing by additional counsel—or at least a delay for plaintiffs to consider whether to file additional briefing.

In addition, the fact that the class is spread across 29 states and Puerto Rico, *see* Rosenthal Report ¶ 82, tbl. 4, Dkt. 615, creates “both a significant and practical difficulty to joinder.” *In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 214 (S.D.N.Y. 2018). And contrary to Takeda’s suggestion, that the parties are aware of the proposed class members’ identities and “whereabouts,” *Ansari v. N.Y. Univ.*, 179 F.R.D. 112, 115 (S.D.N.Y. 1998), does not simply erase coordination concerns, *see CL-Alexanders Laing & Cruickshank v. Goldfeld*, 127 F.R.D. 454, 457 (S.D.N.Y. 1989) (“[D]ispersion makes it difficult for joined plaintiffs to coordinate their legal strategy.”). “[G]eographic dispersion suggests joinder is impracticable,” moreover, “even when putative class members are corporate entities.” *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-MD-2503, 2017 WL 4621777, at *5 (D. Mass. Oct. 16, 2017).

Further, many claimants’ “abilit[ies] . . . to institute individual suits, *see Robidoux*, 987 F.2d at 936, would be limited here because they would “lack a monetary incentive to protect their own interests.” *Ansari*, 179 F.R.D. at 115; *see also Deen v. New Sch. Univ.*, No. 05-CV-7174, 2008 WL 331366, at *4 (S.D.N.Y. Feb. 4, 2008) (interpreting a claimant’s monetary incentive to impact its ability to institute individual suit); *Novella v. Westchester Cnty.*, 443 F. Supp. 2d 540, 547 (S.D.N.Y. 2006) (same), *vacated on other grounds*, 661 F.3d 128 (2d Cir. 2011). For numerous class members, the value of their claims, even once trebled, would likely be less than

the cost of litigation. Under either of the generic entry scenarios, for example, three direct purchasers' damages would be less than \$40,000 once trebled. *See* Rosenthal Report attach. H (noting the estimate share of damages for Hi School Pharmacy Inc., Medical Discount Pharmacy, and Navarro Distribution Center). The Court need not credit the assertion that the relevant cost of litigating here would be \$3.5 million, *see* DPPs' Mot. to Certify at 11 n.60; DPPs' Reply at 3, Dkt. 614, to "make [the] common sense assumption[]," *Jeffries*, 172 F. Supp. 2d at 394, that litigating this complex antitrust case against highly competent opposing counsel would cost more than \$40,000.

In sum, these considerations outweigh the significant financial resources of at least many of the class members. *See* Baker Report tbl. 3, Dkt 615.

The Court thus finds Takeda's objections related to the DPPs' motion meritless and otherwise finds no clear error in the relevant portions of the Report.

CONCLUSION

For the foregoing reasons, the Court adopts the recommendation that it grant the class certifications motions in *In re Actos End Payor Antitrust Litigation*, No. 13-CV-9244 and *In re Actos Direct Purchaser Antitrust Litigation*, No. 15-CV-3278.

As to the former case, the following class is certified:

All entities that, for consumption by their members, insureds, or beneficiaries, paid and/or provided reimbursement for some or all of the purchase price of Actos or generic pioglitazone in the [Class States], other than for resale, at any time from January 17, 2011 through and until December 31, 2015; and all individuals who paid for some or all of the purchase price of Actos in the [Class States] at any time from January 17, 2011 through and until December 31, 2015.

The class excludes (1) Defendants and their subsidiaries and affiliates; (2) federal and state governmental entities; (3) judges assigned to this case and their chambers' staff and any members of the judges' or chambers staff's immediate family; (4) Defendants' officers, directors, and

employees; (5) individuals who after August 17, 2012 purchased only ACTOS and did not purchase generic pioglitazone; and (6) any “flat copay” consumers who purchased ACTOS only via a fixed dollar copayment that does not vary on the basis of the drug’s status as brand or generic.

As to the latter case, the following class is certified:

All persons or entities in the United States and its territories and possessions, including the Commonwealth of Puerto Rico, who purchased Actos or its AB-rated generic equivalent directly from Defendants or any generic manufacturer at any time on or after January 17, 2011 through January 31, 2013.

The class excludes (1) Defendants and their officers, directors, management, employees, subsidiaries, and affiliates; (2) all governmental entities; (3) Drogueria Bayamon and Drogueria Central; as well as (4) Belldina’s Healthmart Pharmacy.

The Clerk of Court is respectfully directed to terminate the motions pending at Docket Entries 584 and 586.

SO ORDERED.

Dated: September 30, 2024
New York, New York

A handwritten signature in blue ink, appearing to read 'Ronnie Abrams', is written over a horizontal line.

Ronnie Abrams
United States District Judge